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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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0 02 81 07/17/99 PRESNELL

9 98-54

SYN 590
ZYGENETICS INC
1401 MOUNT LAKE AVENUE EAST
SEATTLE WA 98102

07/17/99

EXAMINER

ROMEO, D

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED:

12/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/397,846

Applicant(s)
Presnell et al.

Examiner
David Romeo

Group Art Unit
1647



☒ Responsive to communication(s) filed on 17 Sep 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-11 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a polynucleotide encoding a polypeptide, classified in
5 class 536, subclass 23.5.

II. Claims 6-9, drawn to a polypeptide, classified in class 530, subclass 350.

III. Claim 10, drawn to an antibody, classified in class 530, subclass 387.9.

IV. Claim 11, drawn to an anti-idiotypic antibody, classified in class 530,
subclass 387.2.

10 2. The inventions are distinct, each from the other because of the following reasons:

The polynucleotides of Invention I are related to the polypeptides of Invention II by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because
15 they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis or purification from the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

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The polynucleotide of invention I and the antibody of Invention III are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The polynucleotide of invention I and the antibody of Invention IV are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody to which the anti-idiotypic antibody binds. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

The polypeptide of invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

The polypeptide of invention II is related to the antibody of Invention IV by virtue of being the cognate antigen, necessary for the production of the antibody to which the anti-idiotypic

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antibody binds. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

The antibody of invention III is related to the antibody of Invention IV by virtue of being the cognate antigen, necessary for the production of IV. Although III and IV are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because III can be used in another materially different process from the use for production of IV, such as in a pharmaceutical composition in its own right, or for the purification of II.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Claims 1-11 are generic to a plurality of disclosed patentably distinct species comprising
5 SEQ ID NO: 2, 3, 4, 5, 9, 12, 13, 14, 15, 17, 18, 19, 20, 21, or 22. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the
10 examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37
CFR 1.143).

15 8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

5 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO
PRIMARY EXAMINER
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DECEMBER 17, 2000